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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,647	01/10/2006	Robert F. Kelley	P1966R1	7400
9157	7590	03/28/2008		
GENENTECH, INC. 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080			EXAMINER HAMUD, FOZIA M	
			ART UNIT	PAPER NUMBER
			1647	
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			03/28/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/519,647	<b>Applicant(s)</b> KELLEY ET AL.	
	<b>Examiner</b> FOZIA M. HAMUD	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)                         |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application               |
| Paper No(s)/Mail Date _____  | 6) <input checked="" type="checkbox"/> Other: <u>sequence compliance form</u> . |

### **Election/Restriction**

Restriction is required under 35 U.S.C. §121 and 372.

1. This application is a 371 of PCT/US03/019750, filed on 23 June 2003. For applications filed under 371, PCT rules for lack of unity apply.
2. This application contains inventions or groups of inventions which are not so linked as to form a single inventive concept. Under PCT Rule 13.1, the following combinations of claims of different categories are permissible and restriction to one of the following combinations is required:

In accordance with 37 CFR §1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I. Claims 1-10, 12-13, 15-17, 19, 21-32, drawn to an isolated Apo-2 ligand variant polypeptide that has selective binding affinity for the DR4 receptor of SEQ ID NO:3, an isolated nucleic acid encoding said Apo-2 ligand, a vector comprising said nucleic acid, a host cell comprising said vector, a method of producing said Apo-2 ligand, a composition comprising said Apo-2 variant polypeptide and a method of inducing apoptosis in mammalian cells comprising exposing cells expressing DR4 to an effective amount of Apo-2 ligand.

Group II. Claims 1-2, 4-5, 7-32, drawn to an isolated APo-2 ligand variant polypeptide that has selective binding affinity for the DR5 receptor of SEQ ID NO:4, an isolated nucleic acid encoding said APo-2 ligand, a vector comprising said nucleic acid, a host cell comprising said vector, a method of producing

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said Apo-2 ligand, a composition comprising said Apo-2 variant polypeptide and a method of inducing apoptosis in mammalian cells comprising exposing cells expressing DR5 to an effective amount of Apo-2 ligand.

Group III. Claims 34-36, drawn to a method of treating cancer comprising exposing mammalian cancer cells to an effective amount of Apo-2 ligand variant polypeptide.

Group IV. Claims 37-38, drawn to a method of treating an immune-related disease in a mammal, comprising exposing mammalian cancer cells to an effective amount of Apo-2 ligand variant polypeptide.

Pursuant to 37 C.F.R. 1.475(d), this Authority considers that the main invention in the instant application comprises the first-recited product, namely an isolated Apo-2 variant polypeptide that has selective binding affinity for the DR4 receptor of SEQ ID NO:3, an isolated nucleic acid encoding said Apo-2 ligand, a vector comprising said nucleic acid, a host cell comprising said vector, a method of producing said Apo-2 ligand, a composition comprising said Apo-2 variant polypeptide and a method of inducing apoptosis in mammalian cells comprising exposing cells expressing DR4 to an effective amount of Apo-2 ligand. Further, pursuant to 37 C.F.R. 1.475(b)-(d), the ISA/US considers that the materially and functionally dissimilar product of group II, and the additional methods of groups III-IV do not correspond to the main invention. This Authority therefore considers that the several inventions do not share a special technical

feature within the meaning of PCT Rule 13.2 and thus do not relate to a single general inventive concept within the meaning of PCT Rule 13.1.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art by their recognized divergent subject matter as defined by MPEP § 1850. Therefore, an initial lack of unity for examination purposes as indicated is proper.

3. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

***Sequence Rules:***

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. §§ 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through §1.825, because, there is no CRF nor paper copy of the sequence listing. Furthermore, a statement that both are the same is missing. In order for the claims to be examined and searched thoroughly, Applicant must comply with the

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sequence rules under 37 C.F.R. §1.821 through §1.825. See attached sequence compliance form.

***Advisory Information:***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FOZIA M. HAMUD whose telephone number is (571)272-0884. The examiner can normally be reached on Monday-Friday: 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fozia Hamud  
Patent Examiner  
Art Unit 1647  
24 March 2008

/Elizabeth C. Kemmerer/

Primary Examiner, Art Unit 1646